

**COLORADO DEPARTMENT OF PUBLIC
HEALTH AND ENVIRONMENT**

FAMILY PLANNING PROGRAM

CLINICAL SITE VISIT EVALUATION

Agency	
Address	
Program Coordinator/Clinic Manager	
Clinic Services Provider	
Consultant Physician	
Evaluator	
Date of Evaluation	
Date of Report	

Revised 2/2016

Required

Requirements/Recommendations with Source	Yes	No	Comments
Facilities and Accessibility			
Services are provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3) Title X Requirements 9.2) The design of the program's facilities ensures privacy, confidentiality, and regard for self respect and dignity of the served individual during personal interviews, consultations, medical examinations, and treatment. (observe facilities)			
Service site is physically accessible to persons living with disabilities.			
Interpreters/interpretation services are available as needed.			
Translated written material are available			
Service site has English and Spanish after hours phone messages			
Same day or next day appointments are available			
Evening and weekend hours available			
Health Care Services (See QFP)			
Service site provides medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1). This includes, but is not limited to			

Requirements/Recommendations with Source	Yes	No	Comments
emergencies that require referral (Title X Requirement 9.7)			
Service sites must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). (42 CFR 59.5(a)(1) Title X Requirement 9.8)			
Client Services - History			
Complete medical history is documented for all clients and updated at subsequent visits.			
History includes contraceptive risk factors			
Health history documented in EMR is consistent and standardized among providers.			
Client Services-Assessment			
Physical assessment is consistent with national standards for care (ACOG, ACS,ASCCP,USPSTF, CDC)			
Female assessment: BP; Ht/Wt/BMI; breast exam, if appropriate; cervical cancer screening, if appropriate; STI and HIV screening, as indicated			
Male assessment: STI and HIV screening, as indicated, BP, Ht/Wt/BMI			
Contraceptive Services			
Providers follow U.S. Medical Eligibility Criteria (US MEC) for Contraceptive Use and U.S. Selected Practice Recommendations (US SPR) for Contraceptive Use			
Staff and Providers are signed up to receive US MEC and US SPR updates and use related apps and eBook http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception_guidance.htm http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm			
Staff and providers are signed up to receive updates from the Family Planning National Training Centers and use related app			

Requirements/Recommendations with Source	Yes	No	Comments
http://fpntc.org/home http://fpntc.org/training-and-resources/quality-family-planning-services-mobile-app			
There is documentation that clinic staff have received training on QFP			
Clinic offers a broad range of FDA approved contraceptive methods either on-site or by referral (Section 9.8 and 42 CFR 59.5(a)(1))			
<ul style="list-style-type: none"> Barrier methods 			
<ul style="list-style-type: none"> Consistent and correct use of condoms is encouraged, as appropriate 			
<ul style="list-style-type: none"> IUCs 			
<ul style="list-style-type: none"> Hormonal contraceptives 			
<ul style="list-style-type: none"> Fertility awareness methods including natural family planning 			
<ul style="list-style-type: none"> Emergency contraception 			
This program does not provide abortion as a method of family planning (Title X sec 1008, 300 a-b)			
In determining the appropriate method of contraception, the personal preference of the client receives prime consideration unless the method selected has medical contraindications. Contraindications are explained to the clients (review client medical records)			
Agency offers same day LARCs when appropriate			
A 3 month revisit is provided, if indicated, for clients new to a method (OC, Ortho Evra, Nuva Ring, Depo Provera, Nexplanon) (See US SPR)			
During return visits an interim history is taken (especially for estrogen containing methods), including but not limited to			
<ul style="list-style-type: none"> Satisfaction with method 			
<ul style="list-style-type: none"> Side effects or other problems 			

Requirements/Recommendations with Source	Yes	No	Comments
<ul style="list-style-type: none"> Change in health status or medications that would change the appropriateness of method 			
<ul style="list-style-type: none"> Does client wish to change method? 			
Blood pressure if indicated			
Laboratory procedures are performed as indicated			
IUC clients are scheduled to return no later than 3 months following insertion, if indicated			
IUC recheck exams includes visualization of the cervix and bimanual exam (See US SPR)			
<ul style="list-style-type: none"> Satisfaction with method 			
<ul style="list-style-type: none"> Side effects or other problems 			
<ul style="list-style-type: none"> Change in health status or medications that would change the appropriateness of method 			
<ul style="list-style-type: none"> Does client wish to change method? 			
<ul style="list-style-type: none"> Lab procedures performed as indicated 			
Permanent Sterilization			
Federal sterilization regulations are complied with when sterilization is performed or arranged for by the family planning program. [42 CFR Part 50, Subpart B]			
Counseling and consent process for sterilization assures that the client's decision is completely voluntary			
Agency uses Federal Sterilization Consent. Consents are completed correctly. Required signatures: individual sterilized, interpreter, person obtaining consent, and physician performing the sterilization.			
Contraceptive Method Education/Counseling:			

Requirements/Recommendations with Source	Yes	No	Comments
Information on all contraceptive methods, benefits, risks, effectiveness and potential side effects provided to clients.			
Clients provided CDPHE family planning booklet			
Client centered counseling is provided, including written material (QFP Appendix C). 1) establish and maintain rapport with the client, 2) assess the client's needs and personalize discussions accordingly, 3) work with the client interactively to establish a plan, 4) provide information that can be understood and retained by the client, and 5) confirm client understanding.			
Tiered approach to method counseling used, starting with most effective method first			
For clients chosen method there is a process in place for ensuring and documenting client understanding of: <ul style="list-style-type: none"> • Instructions in correct use of method • Method benefits and risks • Effectiveness of method • Potential side effects and how to manage • Possible complications and danger signs and symptoms of method • How to seek emergency care if needed • How to discontinue method • Except for condoms, method does not protect against STIs (See QFP) 			
Counsel client regarding quick start of contraceptive method, when indicated (See QFP)			
Pregnancy Testing and Counseling Services (See QFP)			
Service site must provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a)(5) Title X Requirement 9.10)			
Pregnancy testing is provided on site			
Service site must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: <ul style="list-style-type: none"> • prenatal care and delivery; • infant care, foster care, or adoption; and • pregnancy termination. 			

Requirements/Recommendations with Source	Yes	No	Comments
If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5) Title X Requirement 9.11).			
A list of referral sites for all options is available for clients with a positive pregnancy test.			
Clients with a positive pregnancy test who wish to continue their pregnancy are offered initial prenatal counseling and assessment regarding social support			
Clients with a negative pregnancy test who do not wish to be pregnant are offered contraception			
Achieving Pregnancy and Basic Infertility Services (See QFP)			
Provides basic infertility services. Includes initial infertility interview, education, physical exam, counseling and referral. (Section 9.8 and 42 CFR 59.5(a)(1)) (See QFP)			
Preconception Health Services (See QFP)			
One Key Question/reproductive life plan counseling is provided			
Preconception counseling and services are provided regarding future pregnancies, as indicated. (See QFP)			
<ul style="list-style-type: none"> Counseling is provided regarding the benefits of folic acid supplementation 			
STI and HIV Services (See QFP)			
Providers follow current CDC STD Treatment Guidelines for STI screening and treatment			
Staff and providers are signed up to receive email updates to the CDC STD Treatment Guidelines and have related App http://www.cdc.gov/std/default.htm			
Chlamydia and gonorrhea tests are done on all clients requesting IUC insertions, all clients with PID, other clients as indicated by current screening guidelines including woman 24 y.o. and			

Requirements/Recommendations with Source	Yes	No	Comments
younger annually.			
Provides STI/HIV risk reduction counseling,			
Offers education about HIV infection and risks, information about PEP and PrEP and community resources for PEP and PrEP			
Knowledgeable regarding linkage to care for individuals living with HIV			
Offers information about and a strong recommendation for the HPV vaccine, as indicated			
If not using the CDPHE lab or MetroPath, site is reporting CT/GC data to CDPHE STI-HIV Section			
Site reports STI positives and treatments to the CDPHE STI Registry			
Additional laboratory services are available as indicated when required by the specific contraceptive method (FDA or prescribing recommendations) or according to screening recommendations as stipulated in QFP or requested			
<ul style="list-style-type: none"> Serology for Syphilis 			
<ul style="list-style-type: none"> Hepatitis B and C screening 			
<ul style="list-style-type: none"> HIV testing 			
Adolescent Services (See QFP)			
Provides adolescent services (Section 9.8 and 42 CFR 59.5(a)(1))			
Complies with HHS legislative mandates:			
<ul style="list-style-type: none"> Encourages family participation in the decision of minors to seek family planning services 			
<ul style="list-style-type: none"> Provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities 			

Requirements/Recommendations with Source	Yes	No	Comments
Adolescents are counseled about all methods including LARCs and abstinence			
Adolescents are counseled regarding safe sex practices			
Adolescents are counseled/assured regarding confidentiality of their visits			
Services are youth friendly			
Breast and Cervical Cancer Screening (related preventative health services) (See QFP)			
Provides cervical cancer screening according to ASCCP guidelines			
Sign up for email updates and app at http://www.asccp.org/			
Provides breast cancer screening according to current national guidelines			

Requirements/Recommendations with Source	Yes	No	Comments
Client Services-Consents			
Written program and procedure specific informed consents are signed by the client before receiving medical services/methods are (8.1 Voluntary Participation):			
<ul style="list-style-type: none"> Written in a language easily understood by the client 			
<ul style="list-style-type: none"> Available in other than English if applicable 			
<ul style="list-style-type: none"> Contain interpreter information, if indicated. 			
<ul style="list-style-type: none"> General consent form informs clients that services are provided on a voluntary basis 			
<ul style="list-style-type: none"> General consent form informs clients that acceptance of family planning services is not a prerequisite to receiving other services offered by the agency. 			
Medical Emergencies			

Requirements/Recommendations with Source	Yes	No	Comments
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In order to provide services for emergencies that arise outside of clinic hours, the program has medical back-up through liaison with a hospital, clinic or physician or arrangements for emergency care after clinic hours are (Section 9.7).			
Clients are provided instructions on how to access afterhours emergency care.			
Service site staff document how client wishes to be contacted (e.g. for positive STI test result)			
Service site collects emergency contact information for each client			
Site has written internal plans for the management of on-site medical emergencies to include vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. (Section 9.7 and 42 CFR 59.5(b)(1))			
Training for emergencies is available for staff			
CPR training available to staff			
Pharmaceuticals			
A pharmacy protocol is utilized. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.			
<ul style="list-style-type: none"> Protocol is reviewed and signed annually by a Registered Pharmacist 			
<ul style="list-style-type: none"> Inventory control and reconciliation being performed in a timely manner. 			
<ul style="list-style-type: none"> Expiration dates are checked regularly and out of date supplies are removed from the shelves in the presence of the pharmacist. 			

Requirements/Recommendations with Source	Yes	No	Comments
Written expired medication disposal policy.			
<ul style="list-style-type: none"> All clinic locations are individually licensed. 			
<ul style="list-style-type: none"> Agency has or is in the process of developing a 340B Policy and Procedure manual based on Apexus sample P&P 			
<ul style="list-style-type: none"> Agency staff are signed up to receive Apexus 340B and HRSA 340B email updates. 			
<ul style="list-style-type: none"> Treatment medications for non-clients is dispensed from separate non-340B purchased stock (HRSA 340B Program requirement) 			
Referral and abnormal lab follow-up			
Provides for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8) Title X Requirements 9.5)			
Provides for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2) Title X Requirement 9.4).			
Abnormal lab follow up			
All clients in this program are treated or referred for continuing care when their laboratory tests show abnormal findings			
Clients are notified of abnormal lab test results and notification procedure maintains client confidentiality			
All abnormal labs, i.e. Pap tests, Chlamydia, gonorrhea, lipid screens, etc. are followed through a tracking system which includes:			
<ul style="list-style-type: none"> Recommendations for follow up 			
<ul style="list-style-type: none"> Documentation that client received follow up or documentation that client refused follow up 			
Referrals			
Referral recommendations are explained to client			

Requirements/Recommendations with Source	Yes	No	Comments
Program has referral tracking system i.e. log or tickler file as a reminder to staff regarding contacting client and documenting if client has received follow up for referrals and abnormal lab work (if the client was referred for abnormal lab work)			
The program has, by prior arrangement or written agreement (where necessary), a group of agencies to whom clients may be referred, because of problems noted at the time of the history and physical exam or laboratory testing, or because of problems arising as a result of the contraceptive method, or because the clients requested an additional evaluation.			
Program has list of referral sites, which includes name, specialty, address, and telephone number of site. Referral list includes health care providers, local health departments, hospitals, voluntary agencies, health services projects, and other federal programs. List is dated.			
Program provides follow up, either directly or by referral, for the following conditions (Section 9.7 and 42 CFR 59.5 (b)(1)):			
<ul style="list-style-type: none"> Medical problems beyond the scope of the facility including chronic care management 			
<ul style="list-style-type: none"> Emergency care 			
<ul style="list-style-type: none"> Diabetes screening 			
<ul style="list-style-type: none"> HIV/AIDS care and treatment agencies 			
<ul style="list-style-type: none"> Positive STI 			
<ul style="list-style-type: none"> Abnormal cervical cytology 			
<ul style="list-style-type: none"> Pregnancy related services when appropriate 			
<ul style="list-style-type: none"> Future planned pregnancies/preconception counseling 			
<ul style="list-style-type: none"> Infertility work up and/or therapy of an extensive nature 			
<ul style="list-style-type: none"> Clients or partners of clients requesting information about and/or procedure for sterilization if that service is not available on site 			
<ul style="list-style-type: none"> Genetic issues 			
<ul style="list-style-type: none"> Mental health issues 			

Requirements/Recommendations with Source	Yes	No	Comments
• Intimate partner violence			
• Sexual abuse/sexual violence			
• Substance use/abuse drug/alcohol/tobacco			
• Nutrition services			
• Health promotion/disease prevention			
• Referral regarding Medicaid eligibility and enrollment			
Mandatory Reporting/Human Trafficking			
Service site complies with state statute regarding mandatory reporting of child abuse, child molestation, sexual abuse, rape, or incest abuse and intimate partner violence (Section 9.12)			
Program has internal written mandatory reporting policy and human trafficking resources for clients and staff.			
Medical Records			
Service site must have safeguards to ensure client confidentiality. Information obtained by the clinic staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11 Title X Requirements 10)			
The program maintains complete medical records for every client in accordance with accepted professional standards. The medical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling of information, signed by clinician (check client medical records)			
Records are safeguarded against loss or use by unauthorized persons.			
Clients sign a Notice of Privacy Practices (review this notice -available in other languages)			

Requirements/Recommendations with Source	Yes	No	Comments
All client contacts, including phone calls, are documented in the medical record			
Personnel			
Nurses are licensed to practice in the state with current nursing license (review license number and expiration date)			
Physicians providing supervision of personnel are currently licensed to practice in the state (review license number and expiration date)			
Family planning clinical services are performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6) Title X Requirements 8.5.4)			
Services provided operate within written clinical protocols that are in accordance with nationally recognized standards of care and are signed by the physician responsible for the service site. (Title X Requirements 9.6)			
There is a written agreement or job description with the physician describing family planning program responsibilities and functions			
Policy is in place re the percentage of charts cosigned by the medical consultant			
Medical policies, procedures, and protocols are in written form			
Medical policies, procedures, and protocols are reviewed and signed by nursing staff and mid-level providers			
Staff and providers are signed up to receive FPNTC/CTCFP email updates and newsletter for upcoming trainings			
Medical services are provided by mid-level providers (NP, CNM, PA)			
<ul style="list-style-type: none"> • Collaboration according to appropriate act 			
<ul style="list-style-type: none"> • Mid-level providers have prescriptive authority 			
<ul style="list-style-type: none"> • Contract mid-level providers have liability insurance 			
Advanced Practice Nurses and Physician Assistants dispense medications following protocols or according to prescriptive authority.			

Requirements/Recommendations with Source	Yes	No	Comments
Registered nurses dispense medication per chart order or physician standing orders.			
Training provided for clinic support staff (e.g. Medical Assistants) regarding Nursing/Medical delegated tasks.			
Quality Assurance			
Agency has written policy/procedure for infection control that includes cleaning of rooms, instruments, and other equipment.			
Agency follows blood borne pathogens (BBP) protocols and conducts periodic staff training (procedure for work site injuries)			
Documentation of periodic maintenance of clinic equipment such as autoclave, hemocue, scale			
Procedures for ensuring effective sterilization of instruments e.g. spore testing			
Client satisfaction surveys obtained in the last 12 months			
Documentation of internal quality assurance and quality improvement activities			
Laboratory			
Facility has CLIA license appropriate for the testing it conducts			
<ul style="list-style-type: none"> Laboratory manuals are up to date with CLIA standards, including a wet prep procedure 			
<ul style="list-style-type: none"> Proficiency testing is done as indicated by type of CLIA license 			
<ul style="list-style-type: none"> Site uses most current CLIA waived test instructions when performing the tests. The instructions are readily available to staff. 			
<ul style="list-style-type: none"> Staff run controls for the CLIA waived tests performed according to package insert instructions and document the results 			
Lab log is maintained for tracking all labs performed and sent to outside lab.			
<ul style="list-style-type: none"> Lab log reflects receipt of results 			
<ul style="list-style-type: none"> All results are dated and initialed upon 			

Requirements/Recommendations with Source	Yes	No	Comments
receipt			
<ul style="list-style-type: none"> There is a system for tracking labs in EMR 			

Describe observed clinic flow: